[redacted]

From: Pan, Wenseng Wendy <[redacted]
Sent: 23 March 2018 00:11
To: response
Subject: Consolidated Comments from the BayHelix Group based on a survey of 125 people
Attachments: Represented Industry Groups.jpg; Breakdown of Survey Participants' Companies.png; BayHelix Survey Report (with names redacted).docx.pdf; BayHelix Comments on HKEX Biotech Listing Guidelines (March 19 2018).pdf

First of all, on behalf of the BayHelix Group and many members of the life sciences industry in China, we would like to thank Charles and the HKEX for taking this initiative to open the door for the Chinese biotech companies to access the capital market in HK. This is a historic step as it would more or less complete the circle of the Chinese life sciences ecosystem by providing a very critical link.

Attached are our comments on HKEX's proposed biotech listing rules and guidelines (attachment 4). Our comments are largely directed to some implementation details, not on the framework, which we think is appropriate and in excellent shape. To ensure our comments reflect the collective thoughts of a broad group in the industry, we have submitted our proposed comments to the BayHelix Group in a survey form and shared our survey with 新药创始人俱乐部and 药促会 as well. 125 people participated in the survey, 43% of which are representatives of privately owned biotech companies and 30% of which are representatives of funds (23% are biotech specialty funds and 7% are general funds). See attachments 1, 2 and 3 for details about the survey. The survey result can also be accessed at http://www.wenjuan.com/r/QvIN7z?pid=5aa4cdfea320fc96bc70ba96&vcode=48018ed92bd7d15e132c54c5d16d0d86

Please let us know if you have any questions or need any clarifications about our comments.

BayHelix Task Force on HKEX Biotech Listing Rules

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BayHelix Survey of Proposed Comments to HKEX on draft Biotech Listing Rules

1. The draft guidelines require a company to have "durable patents", which is not a recognized legal term and its meaning is unclear. In addition to patents, exclusive patent licenses and regulatory exclusivity and data exclusivity are important. We suggest that Paragraph 74(e) be revised as follows: "it must have patent(s), patent application(s) and/or intellectual property rights (including exclusive licenses under the foregoing intellectual property rights), together with market exclusivity, if any, that would confer exclusivity to its Core Product(s) in commercialization for a reasonable period of time." Do you agree with the foregoing proposed comment?

The draft guidelines require a com
pany to have "durable patents", whi
ch is not a recognized legal term and its meaning is unclear. In add
...
答题人数 125

选项	回复情况
Yes	118
No	7

回答人数 125

2. If you answer to the foregoing Q1 is "no", please provide your reason and suggested revision here.

答案
1. Should market exclusivity be defined better? For instance, regional or global if licensed in.
2. The proposal leaves too much room for the company to fudge its qualification to meet a key IP requirement. Suggest replacing it with a more verifiable standard of "durable patent", i.e. "the company must have granted patent(s) that would confer market exclusivity to the company's Core Product(s) in its key markets for a duration of at least eight years from product launch".
3. If a company has a trade secret, would it still be adequate?
4. Is the language above intended to be vague? If a company has patents in Brazil only, for example, it would meet this requirement correct? Also, what about a company based solely on in-licensing. They would need to have IP assigned to meet the listing requirements?
5. The proposed change will not apply in the case of biosimilar, for example. In addition, many Chinese biotechs do not have original patents but granted licenses to use.

6. sometimes co-exclsivity can be really big market， especially WW rights
7. I agree largely with the revision. However pls note that Market exclusivity could be obtained independently of patent right, e.g. data exclusivity from a trial 行政保护 for pedriatric use.
8. it must have at least one of the following: a. #1. patent(s), b. #2. patent application(s), c. #3. intellectual property rights obtained through technology transfer or licensing or other agreement or arrangement by which the ListCo or any of its subsidiaries or affiliates is granted certain exclusivity (e.g., geographical exclusivity or shared geographical exclusivity, or product or type of use exclusivity) under the foregoing intellectual property rights, d. #4. marketing exclusivity already granted or is reasonably expected to be granted by a regulator upon approval of its Core Product(s) in at least one market, e. #5. data exclusivity #that would confer exclusivity to its Core Product or at least one of its Core Product(s) when and if such Core Product is approved for commercialization for a reasonable period of time. f. #Notes: In the U.S., it is typical for a biotech company to get listed based on a license to a patent application (not even an issued patent yet). Exclusivity is not conferred only by patent or patent applications, but also by marketing exclusivity by FDA or data exclusivity in the drug application and approval process. g. #Exclusivity requirement shall be limited to only one Core Product of the ListCo. It is not reasonable to expect ListCo to have exclusivity to all of its Core Products. It is very typical for a biotech company to have only one Core Product with exclusivity, while its other Core Product(s) (if any) do not. h. #Finally, it is better to clarity that the Core Product needs not to be commercialized at the time of IPO. In the US, very typical for clinical trial stage biotech to get listed (i.e., Core Product is still years away from possible approved for commercialization). i. #Note not all regulators around in the world grant (or expected to grant) marketing exclusivity. So need to clarify it is from at least one market. #
correct the unclear term into right one

受访人数 9

3. The draft guidelines permit, in a spin-off's HK IPO, the use of "collaboration with other established RD companies" as a substitute to the "Sophisticated Investor" requirement. We suggest that normal companies (i.e. non spin-off) be permitted to use such substitution as well. In addition, the "collaboration" substitute should be limited to a company's out-licensing of its product/technology to a big pharma, not an in-licensing based collaboration. Do you agree with the foregoing proposed comment?

The draft guidelines permit, in a spin-off' s HK IPO, the use of "collaboration with other established RD companies" as a substitute to t...

答题人数 125

选项	回复情况
Yes	98
No	27

回答人数 125

4. If your answer to the foregoing Q3 is "no", please provide your reason and suggested revision here.

答案	
1.	I broadly agree with the concept in the revised answer but want to Note both investors and r&d collaborators can stop funding at any time. It's less likely if the investor is sophisticated. But big pharma R&d collaborators can decide to return the product or stop the project and there are no more proceeds back to the company. We have seen this many times in history
2.	There is no need to be so superstitious to large pharmaceutical companies. licensed in product could also be good if
3.	The concept of collaboration with big pharma is pretty broad. If a non-spin off company were to have a relatively small large pharma "collaboration" for say a very early asset with minimal economics and say, just an option to proceed forward after a certain collaboration period, I would be slightly concerned if there were not "sophisticated investors" also involved.
4.	May want to include "partnership" in addition to collaborations
5.	It's difficult to define "established R&D companies ". #Alternative could be amount of out-license fee or/ and collaboration fee.
6.	A full disclosure will be more important than the proposed restrictions.
7.	One sophisticated investor is not a high bar and there is no need to reduce it further
8.	I would consider in licensing also a viable collaboration.
9.	Collaboration should be limited to a relationship that the big pharma commits its assets in a deal structure including licensing, joint-venture or promotion partnership, to exchange for the commercial and IP rights of biotech's Product.
10.	Did not see clearly the " spin off " position and the in licensing out licensing correlation.
11.	Should allow both

12.	A spin-off also has investors right ? At least the big Pharma who spins it off will have substantial equity. Big Pharma can be counted as a sophisticated investor
13.	Collaboration substitute should not be limited to out-licensing to "Big Pharma" - it should also include out-licensing to innovative biotechs over a certain size (market cap, etc).
14.	Define "big pharm"
15.	Both out-licensing and in-licensing based collaboration can be counted.
16.	could include an in-licensing collaboration as well.
17.	Public investors are new to biotech industry. Keeping "sophisticated investor" is important, but clearly the term needs to further defined.
18.	You should define big Pharma as those pharmaceutical companies whose global sales ranked in the top 20 in the world
19.	Strategic partnerships are complex and not a direct endorsement of the standalone value of the entity. These situations arguably require sophisticated investors even more to ensure independence from its parents.
20.	Suggest to revise this requirement and may present multiple options including credible investor and collaboration with credible R&D institution as favorable consideration for IPO qualification.
21.	Hard to define what is a Big Pharma. Will the largest pharma company in Vietnam be counted as a Big Pharma, for example?
22.	The definition of "established R & D company" is not clear, and subject to various interpretation.
23.	Why not using out-licensing or out-partnering directly? Collaboration relationship is weak and could be ambiguous.#
24.	Need to define "big pharma"
25.	It should be a long term value creation for such licensing for the company. Or it will be a problem for the long term growth of the company
26.	Hw do you define big pharma? One with launched products in major markets? Top 20 in sales? Is Hengrui a big PHARMA? UCB?
27.	Not sure about the direction of licensing can be simplified like this. For spinoffs, parent normally license to sub; for standalone companies, it can be either way. Either as proof of list-co's R&D capability, or the in-licensed technology comes from credible sources.
28.	Collaboration with established R&D companies or sophisticated investors
29.	in-licensing counts? otherwise, Zai Lab would not be qualified for HK IPO?
30.	#I agree with your suggestion that normal companies (i.e. non spin-off) be permitted to use such substitution as well. #In addition, I suggest the "collaboration with other established R&D companies:" to be expanded to "collaboration with other established R&D companies, or university(ies), or research institute(s), or clinical trial center(s) or hospital(s)." The rationale is that in the U.S., very typical for a biotech company to get listed based on R&D collaboration with a university, research institute or hospital. In fact, that's the spirit of biotech nowadays. Before IPO, conduct R&D through collaboration, obtain IP rights and then after IPO, use IPO proceeds to build its own R&D facility – labs and manufacturing facilities. #

31.	Following legal suggestion
32.	Collaboration is a very loosely defined term and easy to bypass. Having said that, sophisticated investor is the same

受访人数 32

5. Paragraphs 75(a) and 75(b) of the Consultation Paper state that the achievement of the "beyond the concept stage" status by a Core Product could be demonstrated by the fact that "the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials." As there is a growing trend in using combined-phase trials (also known as adaptive or seamless clinical trials), especially in oncology, we suggest that the following language be added to the end of Paragraphs 75(a)(i) and 75(b)(i) to cover such trials which are not divided into Phase I and Phase II, "or it has completed certain clinical trials, which results demonstrate acceptable safety profile and provide preliminary evidence of efficacy in targeted patients." Do you agree with the foregoing proposed comment?

Paragraphs 75(a) and 75(b) of the Consultation Paper state that the achievement of the "beyond the concept stage" status by a Core Produ
...
答题人数 125

选项	回复情况
Yes	111
No	14

回答人数 125

6. If your answer to the foregoing Q5 is "no", please provide your reason and suggested revision here.

答案	
1.	Again I agree with the edit but for 505b2 products they may not have been clinical trials done for poc. By very nature of being a 505b2 it just has to do a p3 trial #
2.	Targeted patient "population"
3.	The proposed new language is substantially different than the original language as the objective of ph1 is mainly to assess safety. Although the recent IO success based on large ph1/2 studies (I filed the durvalumab BLA based on 1100 pts ph1), FDA has faced resources and review challenges with this approach and start to discourage that.

	Given the traditional sample size of ph1, the chance of seeing activity in the context of oncology is dismal, therefore it's different from the language on commencing ph2.
4.	Agree with the suggestion. But the trials have to be IND approved trials.
5.	The proposed replacement would make it easy for companies to fudge compliance with clinical development requirement. A bright line test would be better.
6.	the bar is set too low
7.	The combined phase 1 and 2 trial represents a small percentage of all new drug trials. Even there was some successes with this new trial design, it still carries significant risks.
8.	I am OK with the statement but should add "Or competent authorities has agreed to have a combined Phase I and II trials for the relevant drug candidates.
9.	or take the number of enrolled patients as a parameter
10.	Typically the concept to be proved in clinical trials include both safety and efficacy, and this higher requirement is healthy for a young market. Then it is practical to use an agreement between the biotech and regulatory agents, such as a meeting minute with CFDA or special protocol agreement (SPA) with the US FDA as a proof of the product' beyond-concept stage and its readiness for a pivotal clinical trial.
11.	The original phase 2 ready goes beyond safety profile with approved efficacy testing protocol which should be added. Some of the biotech products such as medical device and diagnostic kits have different regulatory requirement and may not be the same as the process of Phase 1-3 for drug candidates.
12.	First in human in the territories of rights is the most objective measure for clinical progress
13.	The phrase ", of which results demonstrate..." may not provide a clear enough criteria for the HKEX officials to make a judgement or decision. The concert is too subjective even for the professionals, not to mention the outsiders. An objective and clear standard need to be in place.
14.	In the case of 505b2 company can submit application for approval if the phase 1 results meet the requirements.
15.	"or it has completed "proof of concept" clinical trials, which results demonstrate acceptable safety profile and provide preliminary evidence of efficacy in intended patients."
16.	Your suggestion is great. Suggest we also add some clarification to Phase II in HKEx language to read: a. #"the relevant Competent Authority has no objection for it to commence Phase II (including a combined Phase I/IIa or combined Phase I/II) or later clinical trials, or if the Core Product is in the field of oncology or rare diseases, the relevant Competent Authority has no objection for it to commence Phase I clinical trial." b. #I changed your suggested language because it may be construed as going backward from HKEx draft language in that HKEX used the term has not objection for it to commence Phase II whereas your suggestion requires completion of certain clinical trials. A real life example, in rare diseases field, very typical to apply to the FDA to start a combined Phase I/II (or combined Phase I/IIa) clinical trial before any clinical trial at all. Therefore, based on HKEx language, it may be okay (still need to clarify that such no objection to commence Phase II includes a combined Phase I/IIa or combined Phase I/II), whereas your suggested language it would not be okay because it has not done any clinical trial yet. #

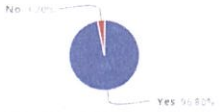
17.	this is a tricky statement and in the end will be a judgement from reviewers based on scientific and clinical evidence
18.	Expand into more complex situation
19.	What about a licensed-Ph II asset that has not started trials in China but the original owner (or the co-development partner) has started PhII in other countries?

受访人数 19

7. The Exchange has given examples of information that are required to be disclosed in the listing applications and the interim and annual reports, but not examples of material information that should be disclosed by a listed Biotech Company on an on-going and timely basis. We suggest that the Exchange also provide a list of examples of information to be disclosed on an on-going and timely basis, such as clinical results, IP litigation, changes in material licensing or partnership transactions. Do you agree with the foregoing proposed comment?

The Exchange has given examples of information that are required to be disclosed in the listing applications and the interim and annual

答题人数 125



选项	回复情况
Yes	121
No	4

回答人数 125

8. If your answer to the foregoing Q7 is "no", please provide your reason and suggested revision here.

答案	
1.	I would suggest examples but these examples should be the sole criteria or only basis for determining material information.
2.	In the US, there are clear guidance on what clinical trials results should be made available within what timeframe. Given there is much sensitivity around it, this particular disclosure should be spelled out clearly or not specifically required rather referring to international or local practice.
3.	How would we define materiality will be important I think.
4.	The disclosure of the mentioned information should be on a voluntary basis.

5.	"clinical results" need to be further defined, e.g., "clinical results that may significantly deviate from the current protocol" or smtg else. Otherwise it is asking for trouble.
6.	a comment: clinical results some time can only be disclosed at the end of trial or predefined interim points. "timely" is difficult to define.
7.	Good suggestion. #This also reminds us of a related point. In the U.S., it is typical for biotech listco to seek confidential treatment from SEC on certain parts of its material agreements, including licensing agreements or patent applications. In fact, if you look at SEC IPO filings, biotech companies sometimes even redact the patent number in the attachments filed in the IPO documents. So, we need to ask HKEx to be mindful about leaving some room for biotech ListCo to seek similar confidentiality treatment and not to make the sensitive terms public (it should still have a good description and disclosure on its patents or applications or licensing agreements in the IPO prospectus but should be allowed to redact key sensitive terms in the attachments).#
8.	Suggest to include adverse events specifically.
9.	good suggestion

受访人数 9

9. The Exchange is considering adding people with experience and expertise in biotech sector to the Listing Committee. Is this sufficient or a separate subcommittee should be formed, at least during the initial period in implementing new biotech listing rules?

The Exchange is considering adding people with experience an d expertise in biotech sector to the Listing Committee. Is t his sufficient or a separate subcommittee should be formed, ...
答题人数 125

选项	回复情况
Adding members with experience and expertise in biotech sector to the Listing Committee is sufficient because these members can address issues unique to the biotech industry and educate other members of the Listing Committee.	42
A separate sub-committee should be formed because (i) it may not be feasible to have a meaningful number of members with the biotech experience and expertise on the Listing Committee, a group with less than five members may not have the experience	83

and expertise broad enough to address complexity of the biotech industry; (ii) in the early stage in implementing the new biotech listing rules, there will be more discussions on policy and practice that are unique to this industry, which may not be efficient or productive if the discussions are conducted in a general meeting of the Listing Committee and (iii) listed biotech companies are also subject to stricter delisting rules.	

回答人数 125

10. Rule 18A.01 defines "Biotech" as "the application of science and technology to produce commercial products with a medical or other biological application." Since the term "biological application" would capture bio-fuel, bio-industrial chemistry, the products of which usually do not require approvals from regulatory authorities such as FDA, CFDA or EMA. We suggest the definition be revised to cover products with "therapeutic, diagnostic and/or prophylactic applications," which is the customary broad definition of "Field" in biotech commercial agreements. Do you agree with the foregoing proposed comment?

Rule 18A.01 defines "Biotech" as "the application of science and technology to produce commercial products with a medica l or other biological application." Since the term "biologic...
答题人数 124

选项	回复情况
Yes	115
No	9

回答人数 124

11. If your answer to the foregoing Q10 is "no", please provide your reason and suggested revision here.

答案
1. Should the word used be "preventative" instead of "prophylactic"?

2.	All sectors whether biotech, "pharmaceutical device" or any other related devices shall all be considered in particular relating to China
3.	Perhaps keep initial definition but caveat that which specific types of biological products would not apply, for example. Classifying as therapeutics could encompass TCM and not sure we want this to be encompassed by the biotech definition.
4.	Should include medical device and other healthcare applications.
5.	therapeutic, diagnostic and/or prophylactic applications for human health.
6.	Extend to non-medical biological application should be fine, as some can be very important in help better living of people and shape up the world.
7.	What about medical device companies?
8.	For human only or include animals? (veterinary products , for food and companion animal? #What about EPA regulated products, like peptides as antifungal for agriculture. Certainly biotech.
9.	Industrial bio companies also require substantial capital to commercialize their innovations and why should be excluded? Does the Nasdaq exclude them?
10.	Agree with your suggestion. But there are two problems a. #1. your suggestion will preclude biotech companies in the field of bio-fuel etc from listing, so we should still keep their language and add yours. b. #2. A big issue with HKEx's language is "to produce commercial products." In the U.S., many biotech companies only focus on R&D or even just R. They are not interested in "producing (or making or manufacturing" or "commercializing" the product. In fact, it is an industry practice and more efficient for these biotech companies to license out, or partner with or sell the pipeline product (not a commercial product) yet to a big pharma which has much stronger sales network and commercialization resources. The HKEx language implies that the biotech company is expected to produce, commercialize and sell the product on its own and get revenue and profits from product sales rather than from licensing, royalty or sale of IP income. This is a fundamental issue which needs to be revised to avoid future policy debate and confusions. Suggest we include the words research and develop (which is widely accepted in the biotech industry) instead of produce a commercial product (biotech is not a traditional manufacturing business!) and emphasize such R&D is for potential application (which is the case before the product is approved and that's why it is called R&D, otherwise biotech companies will be no different from traditional pharma or sales companies). c. #Suggest to change the language to "the application of science and technology to research and develop product(s) with a potential medical or other biological application." Again, the focus of biotech companies should be on R&D of product, not on produce or commercialise a product. #
11.	The proposal is good. It's unclear if you meant adding your proposed language or replacing the language on biological application. I thought the intent was indeed to cover biotech as broadly as reasonably even though therapeutic, diagnostic and/or prophylactic products are what in front of our minds.
12.	add medical devices

13. what about medical devices?

受访人数 13

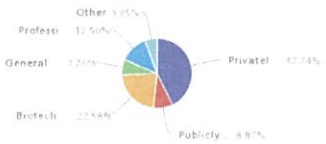
12. Please provide your name and company (optional).

答案
1. redacted

受访人数 71

13. Please describe your company/fund (choose one that is mostly applicable):

Please describe your company/fund (choose one that is mostly applicable):
答题人数 124

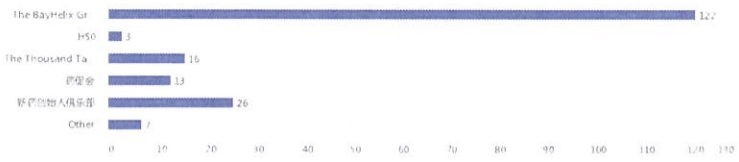


选项	回复情况
Privately owned biotech company	53
Publicly owned biotech company	11
Biotech investment fund	28
General investment fund	9
Professional services company	16
Other	7

回答人数 124

14. Please describe industry organization that you belong to (choose all applicable ones)

Please describe industry organization that you belong to (choose all applicable ones)
答题人数 125



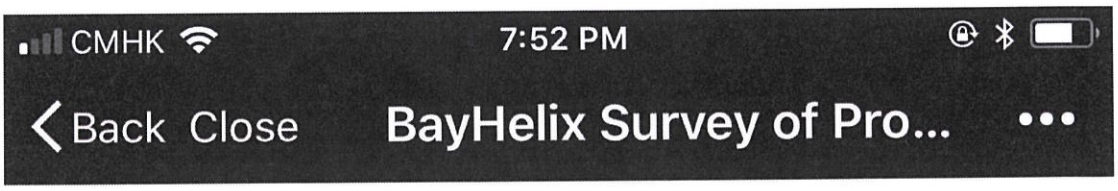
选项	回复情况
The BayHelix Group	122
H50	3
The Thousand Talent Group	16

药促会	13
新药创始人俱乐部	26
Other	7

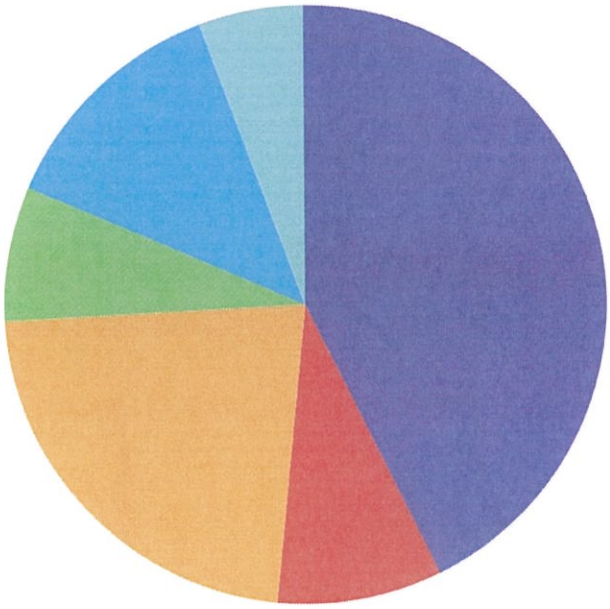
回答人数 125

选项	回复情况
The BayHelix Group	122
H50	3
The Thousand Talent Group	16
药促会	13
新药创始人俱乐部	26
Other	7

回答人数：125



统计报表



选项	回复情况
Privately owned biotech company	42.7%
Publicly owned biotech company	8.8%
Biotech investment fund	22.5%
General investment fund	7.2%
Professional services company	12.9%
Other	5.6%

BayHelix Comments on HKEX Proposed Biotech Listing Rules and Guidelines

1. Paragraph 74(e) of the Consultation Paper states that "*it must have durable patent(s), registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s)*."

   Comment 1: "Durable patents" is not a recognized legal term and its meaning is unclear. In certain small circles of the industry, "durable patents" refers to composition of matter patents of active pharmaceutical ingredients, which is inconsistent with the Exchange's intention to cover 505b2 products, biosimilars, medical devices and other products (See Paragraph 74).

   Comment 2: An exclusive right in commercializing Biotech Products is a key element to the success of a Biotech Company. Whether a patent, patent application or other intellectual right is strong or "durable" is based on its ability or potential ability (in terms of time period and scope) in providing exclusivity. Regulatory exclusivity and data exclusivity could also provide exclusivity to the owner of a Biotech Product, thus should also be considered.

   We suggest that Paragraph 74(e) be revised as follows:

   "it must have patent(s), patent application(s) and/or intellectual property rights (including exclusive licenses under the foregoing intellectual property rights), together with market exclusivity, if any, that is expected to confer exclusivity to its Core Product(s) when it is commercialized for a reasonable period of time."

2. Paragraph 74(g) of the Consultation Paper states that "*it must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor at least six months before the date of the proposed listing (which must remain at IPO). This factor is intended to demonstrate that a reasonable degree of market acceptance exists for the applicant's R&D and Biotech Product. Where the applicant is a spin-off from a parent company, the Exchange may not require compliance with this factor if the applicant is able to otherwise demonstrate to the Exchange's satisfaction that a reasonable degree of market acceptance exists for its R&D and Biotech Product (for example, in the form of collaboration with other established R&D companies).*"

   Comment 1: As the underlying justification is the same, alternative ways to demonstrate market acceptance should not be limited to a spin-off situation. The alternative approach should be allowed in non-spin-off situations as well.

   Comment 2: A "collaboration with other established R&D companies" could cover many forms of collaborations. In the life sciences industry, a Biotech Company's out-licensing of its product/technology to an established life sciences company is usually considered a validation of the Biotech Company's product/technology, but not a collaboration based on

a Biotech Company's in-licensing of an established life sciences company's product/technology.

We suggest that Paragraph 74(g) be revised as follows:

"it must have previously received meaningful third party investment (being more than just a token investment) from at least one Sophisticated Investor at least six months before the date of the proposed listing (which must remain at IPO). This factor is intended to demonstrate that a reasonable degree of market acceptance exists for the applicant's R&D and Biotech Product. The Exchange may not require compliance with this factor if the applicant is able to otherwise demonstrate to the Exchange's satisfaction that a reasonable degree of market acceptance exists for its R&D and Biotech Product (for example, in the form of out licensing its platform technology or Biotech Product to established life sciences companies)."

3. Paragraphs 75(a) and 75(b) of the Consultation Paper state that the achievement of the "beyond the concept stage" status by a Core Product could be demonstrated by the fact that "*the relevant Competent Authority has no objection for it to commence Phase II (or later) clinical trials*." As there is a growing trend in using combined-phase trials (also known as adaptive or seamless clinical trials), especially in oncology, we suggest that the following language be added to the end of Paragraphs 75(a)(i) and 75(b)(i) to cover such trials which are not divided into Phase I and Phase II trials, "*or it has completed certain clinical trials, which results demonstrate acceptable safety profile and provide preliminary evidence of efficacy in targeted patient populations*."

4. Paragraph 83 of the Consultation Paper and Rule 18A.04(a) list information that an Applicant is required to disclose in its listing application. Rule 18A.07 lists information that a listed Biotech Company is required to disclose in its interim and annual reports.

   Comment 1: If the Exchange has given examples of information that are required to be disclosed in the listing applications and the interim and annual reports, it would be desirable that the Exchange also provides examples of material information that should be disclosed by a listed Biotech Company on an on-going and timely basis.

   Comment 2: As certain information such as clinical results disclosed by a Biotech Company at an industry conference arguably is not "inside information" because it has been disclosed to the public at an industry conference, it may not squarely fall under the definition of "Price Sensitive Information" thus not be subject to the statutory disclosure requirement, it would be in the interest of investors if such information is required to be disclosed as "Price Sensitive Information". This approach could also be helpful to company and its officers so they can steer away from potential criminal liabilities for failure to make such disclosure.

   Comment 3: In addition to clinical results, we suggest that adverse events, IP litigation, changes in material licensing or partnership transactions be listed as examples of information that are required to be disclosed on an on-going and timely basis.

5. The Exchange is considering adding people with experience and expertise in biotech sector to the Listing Committee. Is this sufficient or a separate subcommittee should be formed, at least during the initial period in implementing new biotech listing rules?

   A1: Adding members with experience and expertise in biotech sector to the Listing Committee is sufficient because these members can address issues unique to the biotech industry and educate other members of the Listing Committee.

   A2: A separate sub-committee should be formed because (i) it may not be feasible to have a meaningful number of members with the biotech experience and expertise on the Listing Committee, a group with less than five members may not have the experience and expertise broad enough to address complexity of the biotech industry; (ii) in the early stage in implementing the new biotech listing rules, there will be more discussions on policy and practice that are unique to this industry, which may not be efficient or productive if the discussions are conducted in a general meeting of the Listing Committee and (iii) listed biotech companies are also subject to stricter delisting rules.

6. Rule 18A.01 defines "Biotech" as "*the application of science and technology to produce commercial products with a medical or other biological application*." Since the term "biological application" would capture bio-fuel, bio-industrial chemistry, the products of which usually do not require approvals from regulatory authorities such as FDA, CFDA or EMA. We suggest the definition be revised to cover products with "therapeutic, diagnostic and/or prophylactic applications," which is the customary broad definition of "Field" in biotech commercial agreements.